DRAFT STAFF ASSESSMENT OF THE PROPOSED MINNESOTA PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS AS DESCRIBED IN THE REQUEST FOR AN AGREEMENT

This Draft Staff Assessment examines the proposed Minnesota Program with respect to the ability of the program to regulate the possession, use, and disposal of radioactive materials subject to the Atomic Energy Act of 1954 (Act), as amended.¹ The Draft Staff Assessment was performed using the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (referred to below as the "criteria")² using an internal procedure developed by the Office of State and Tribal Programs (STP). Each criterion, and the NRC Draft Staff Assessment related thereto, is addressed separately below.

OBJECTIVES

1. Protection. A State regulatory program shall be designed to protect the health and safety of the people against radiation hazards.

The proposed Minnesota Program for regulating agreement materials would be located within the existing Radiation Control Unit (RCU) of the Section of Asbestos, Indoor Air, Lead, and Radiation, in the Division of Environmental Health, an organizational unit of the Minnesota Department of Health (MDH). The Department's current radioactive materials program has responsibility for registration, inspection, emergency response, and fee collection for naturally-occurring or accelerator-produced radioactive materials (NARM). The RCU also has responsibility for the regulation of electronic product radiation and non-ionizing radiation at academic, medical, and industrial facilities. The RCU also conducts environmental sampling statewide and near the two Minnesota nuclear power plants. Under the proposed Agreement, the RCU would assume responsibility for licensing and inspecting byproduct, source, and small quantities of special nuclear material.

An Intra-Agency Agreement between the RCU and the Public Health Laboratory within the MDH has been established to provide laboratory analysis of radioactive material samples. In addition, an Interagency Agreement between the MDH and the University of Minnesota, Department of Environmental Health and Safety, ensures that the RCU has radiological waste disposal support.

ATTACHMENT 1

¹According to paragraph (a) of § 274, the radioactive materials subject to the Act are byproduct, source and special nuclear materials.

²NRC Statement of Policy published in the <u>Federal Register</u>, January 23, 1981 (46 FR 7540-7546), a correction was published July 16, 1981 (46 FR 36969) and a revision of Criterion 9 published in the Federal Register, July 21, 1983 (48 FR 33376).

The authority to issue, amend, suspend, or revoke licenses, place conditions and to issue orders or assess administrative fines is vested by Statute in the Commissioner of the MDH.

The NRC staff review verified that the Minnesota Program design for distributing regulatory responsibilities to the program staff is similar to designs used successfully in other Agreement States, and that all necessary program elements have been addressed.

Although there are other Minnesota agencies, besides the MDH, that have been historically delegated by the State certain authority to regulate activities involving radioactive materials, those other agencies are not given any authority under the Agreement. The staff has determined that activities by these other agencies will not impact the Agreement.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1, Statutory Authority and Section 4.1.2, Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. At this Internet site see the following Mn. Stats. 115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400. In addition, see Minnesota documents at: http://www.me3.org/issues/nuclear/eqbnukes1.html

http://www.me3.org/issues/nuclear/eqbnukes2.html

http://www.me3.org/issues/nuclear/egbnukes3.html

http://www.leg.state.mn.us/lrl/issues/prairieisland.asp

http://www.puc.state.mn.us/docs/orders/04-0001.pdf

http://www.house.leg.state.mn.us/hrd/pubs/nucwaste.pdf

http://www.puc.state.mn.us/docs/briefing_papers/b05-0022.pdf

http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

RADIATION PROTECTION STANDARDS

2. Standards. The State regulatory program shall adopt a set of standards for protection against radiation which shall apply to byproduct, source and special nuclear materials in quantities not sufficient to form a critical mass.

Under the proposed Minnesota Program, the authority to promulgate rules for the control of radiation rests with the MDH in accordance with Mn. Stat. 144.12, *Regulations, enforcement, licensees, fees.* The MDH is also provided radiation control authority by Mn. Stats., 144.1202, and 144.1203, Training, rulemaking. Minnesota also has ancillary statutes that relate to MDH activities, dealing with record and data keeping, giving false information, surety requirements, inspection, fees, and other matters.

The NRC staff verified that the MDH adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150 into Minnesota Rules Chapter 4731, Radiation Safety, June 24, 2004 and January 1, 2005. Therefore, MDH has adopted an adequate and compatible set of radiation protection regulations which apply to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass.

Minnesota does have additional statutes, identified in the staff's review, which are not part of its program for the regulation of agreement materials but which potentially intrude upon areas reserved to the NRC. Whether or not these Minnesota statutes are preempted by Federal law, they concern areas over which Minnesota is not seeking authority as part of this Agreement, and the staff is satisfied that these statutes will not affect Minnesota's regulation of agreement material. The staff view is that these statutes are outside the scope of the Agreement and therefore, not within the scope of inquiry as to this criterion.

The staff has, however, considered these statutes and program elements in making its determination as to this criterion. For example, a radiation dose standard of 0.054 millirem/year for the Prairie Island Nuclear Power Plant (Prairie Island) independent spent fuel storage installation (ISFSI) appears to have been agreed upon as the result of a negotiation between the State of Minnesota and the licensee and was memorialized in an order by the Minnesota Public Utility Commission (MPUC). In December 2004, NRC initiated discussions with the MDH regarding the radiation dose standard at the Prairie Island ISFSI and a potential similar radiation dose standard at the proposed Monticello Nuclear Power Plant (Monticello) ISFSI. When the MDH became aware of NRC's concerns with respect to the proposed Monticello ISFSI, they interacted with the Minnesota Environmental Quality Board (MEQB). MDH informed the MEQB that radiation dose standards at the proposed Monticello ISFSI would be reserved to the NRC. Based on this information, the MEQB revised the Environmental Impact Statement Scoping Decision to reflect NRC's jurisdiction at the ISFSI. The Monticello Decision provides that Federal regulations preempt State regulation of radiological health and safety standards applicable to nuclear power plants and ISFSIs. This effort by the MDH iterates a proactive approach with respect to assuring that preemption issues are dealt with in an acceptable manner. Therefore, the staff is satisfied that Minnesota will not regulate in areas reserved to the NRC in matters concerning or affecting the proposed Agreement or materials regulated under the Agreement.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1 and Section 4.1.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp.) In addition, see Minnesota documents at: http://www.me3.org/issues/nuclear/eqbnukes1.html http://www.me3.org/issues/nuclear/eqbnukes2.html

http://www.me3.org/issues/nuclear/egbnukes3.html

http://www.leg.state.mn.us/lrl/issues/prairieisland.asp

http://www.puc.state.mn.us/docs/orders/04-0001.pdf

http://www.house.leg.state.mn.us/hrd/pubs/nucwaste.pdf

http://www.puc.state.mn.us/docs/briefing_papers/b05-0022.pdf

http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf

3. Uniformity of Radiation Standards. It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurement and radiation dose. There shall be uniformity on maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by 10 CFR Part 20 of the NRC regulations based on officially approved radiation protection guides.

Minnesota, by statute, must promulgate and enforce rules for the regulation of byproduct, source, and special nuclear material that are in accordance with Section 274 of the Act, as amended. The State has adopted a rule compatible with 10 CFR Part 20. The staff review verified that the Minnesota rules' technical definitions and terminology; units of measurement and dose; and permissible doses, levels of radiation and concentrations of radioactivity are consistent with those in NRC regulations.

Minnesota has applied a 0.054 millirem/year radiation dose standard to the Prairie Island ISFSI facility, which is discussed in the staff's analysis of Criterion 2, above. For the reasons stated there, the NRC staff is satisfied that this radiation dose standard will not affect regulation of material under the proposed Agreement.

In addition, the staff review further noted that Mn. Stat. 116C.71 contains definitions different from the NRC definitions with respect to the terms "Byproduct Material," "Disposal," "High Level Waste," "Radiation," and "Radioactive Waste." However, the statute states that these definitions are applicable only for the purposes of sections 116C.71 to 116C.74 of the Minnesota Statutes, which do not relate to the MDH, the State agency responsible for carrying out the proposed Agreement, or to the regulation of materials under which Minnesota is seeking authority under this Agreement. MDH's regulations, which do apply to agreement material, contain definitions of these terms compatible with those of the Commission. In addition, RCU has in writing assured the staff that it will not apply the definitions in Mn. St. 116C.71 to the regulation of agreement material, and will inform other Minnesota State agencies of the need to conform the statutory definitions to the NRC definitions. Therefore, the staff is satisfied that the Minnesota Program provides for the uniformity of radiation standards and definitions.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1 and Section 4.1.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/Irl/issues/prairieisland.asp.) In addition, see Minnesota documents at: http://www.me3.org/issues/nuclear/eqbnukes1.html

http://www.me3.org/issues/nuclear/egbnukes3.html

http://www.meb.org/issues/huclear/eqphakess.html

http://www.leg.state.mn.us/lrl/issues/prairieisland.asp

http://www.puc.state.mn.us/docs/orders/04-0001.pdf

http://www.house.leg.state.mn.us/hrd/pubs/nucwaste.pdf

http://www.puc.state.mn.us/docs/briefing_papers/b05-0022.pdf

http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf

4. Total Occupational Radiation Exposure. The regulatory authority shall consider the total occupational radiation exposure of individuals, including that from sources which are not regulated by it.

The NRC staff review verified that Minnesota has adopted rules equivalent to the NRC regulations in 10 CFR Part 20, including Subpart C, the occupational dose limits and Subpart D, the dose limits to individual members of the public. Minnesota licensees are required to consider the radiation doses to individuals from all sources of radiation, except background radiation and radiation from medical procedures. Like NRC licensees, Minnesota licensees are required to consider the radiation dose whether the sources are in the possession of a licensee or not.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety, §§ 4731.2020 through 4731.2095.

5. Surveys, Monitoring. Appropriate surveys and personnel monitoring under the close supervision of technically competent people are essential in achieving radiological protection and shall be made in determining compliance with safety regulations.

NRC requires surveys and monitoring pursuant to Subpart F of 10 CFR Part 20. The NRC staff review verified that Minnesota has adopted a rule compatible with Subpart F. Therefore, Minnesota licensees are required to conduct surveys and personnel monitoring to the same standards required of NRC licensees.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety, §§ 4731.2220 and 4731.2230.

6. Labels, Signs, Symbols. It is desirable to achieve uniformity in labels, signs and symbols, and the posting thereof. However, it is essential that there be uniformity in labels, signs, and symbols affixed to radioactive products which are transferred from person to person.

The NRC staff review verified that Minnesota has adopted regulations compatible with NRC regulations in Subpart J of 10 CFR Part 20. Therefore, the radiation labels, signs and symbols, and the posting and labeling requirements in the Minnesota rules are identical to those contained in the NRC regulations.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety, §§ 4731.2300 through 4731.2350.

7. Instruction. Persons working in or frequenting restricted areas shall be instructed with respect to the health risks associated with exposure to radioactive materials and in precautions to minimize exposure. Workers shall have the right to request regulatory authority inspections as per 10 CFR 19, Section 19.16 and to be represented during inspections as specified in Section 19.14 of 10 CFR 19.

The NRC staff review verified that Minnesota has adopted regulations compatible with 10 CFR Part 19.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State(ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety, §§ 4731.1040 through 4731.1060.

8. Storage. Licensed radioactive material in storage shall be secured against unauthorized removal.

The NRC staff review verified that Minnesota has adopted a rule compatible with Subpart I of 10 CFR Part 20.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety, §§ 4731.1040 through 4731.1060.

9. Radioactive Waste Disposal. (a) Waste disposal by material users. The standards for the disposal of radioactive materials into the air, water and sewer, and burial in the soil shall be in accordance with 10 CFR Part 20. Holders of radioactive material desiring to release or dispose of quantities or concentrations of radioactive materials in excess of prescribed limits shall be required to obtain special permission from the appropriate regulatory authority. Requirements for transfer of waste for the purpose of ultimate disposal at a land disposal facility (waste transfer and manifest system) shall be in accordance with 10 CFR 20. The waste disposal standards shall include a waste classification scheme and

provisions for waste form, applicable to waste generators, that is equivalent to that contained in 10 CFR Part 61.

The NRC staff review confirmed that Minnesota has adopted rules that are compatible with Subpart K of 10 CFR Part 20 - Waste Disposal. This regulation deals with general requirements for waste disposal including waste classification, transfer and waste manifests and are applicable to all licensees.

The staff's analysis of Criterion 3, above, identifies Minnesota statutory definitions, separate from the program for the regulation of agreement material (MDH), which are different from NRC definitions of those terms. For the reasons discussed under Criterion 3, the staff is satisfied that those definitions will not affect the regulation of material under the Agreement.

The staff therefore concludes that Criterion 9(a) is satisfied.

(b) Land Disposal of waste received from other persons. The State shall promulgate regulations containing licensing requirements for land disposal of radioactive waste received from other persons which are compatible with the applicable technical definitions, performance objectives, technical requirements and applicable supporting sections set forth in 10 CFR Part 61. Adequate financial arrangements (under terms established by regulation) shall be required of each waste disposal site licensee to ensure sufficient funds for decontamination, closure and stabilization of a disposal site. In addition, Agreement State financial arrangements for long-term monitoring and maintenance of a specific site must be reviewed and approved by the Commission prior to relieving the site operator of licensed responsibility (Section 151(a)(2), Pub. L. 97-425).

The NRC staff review confirmed that Minnesota is not seeking authority to regulate the land disposal of low-level radioactive waste. Therefore, Criterion 9(b) does not apply to Minnesota.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety, §§ 4731.2400 through 4731.2450.

10. Regulations Governing Shipment of Radioactive Materials. The State shall, to the extent of its jurisdiction, promulgate regulations applicable to the shipment of radioactive materials, such regulations to be compatible with those established by the U. S. Department of Transportation and other agencies of the United States whose jurisdiction over interstate shipment of such materials necessarily continues. State regulations regarding transportation of radioactive materials must be compatible with 10 CFR Part 71.

The NRC staff verified that Minnesota has adopted regulations compatible with 10 CFR Part 71 - Transportation. Minnesota does have statutes, separate from its program for the regulation of agreement materials, that pertain to the transportation of radioactive material; however, those

statutes do not apply to the transportation of agreement material. Minnesota's regulations specifically exempt areas of exclusive NRC jurisdiction.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1 and Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety, 4731.0400 through 4731.0424, the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/Irl/issues/prairieisland.asp.)

11. Records and Reports. The State regulatory program shall require that holders and users of radioactive materials (a) maintain records covering personnel radiation exposures, radiation surveys, and disposals of materials; (b) keep records of the receipt and transfer of the materials; (c) report significant incidents involving the materials, as prescribed by the regulatory authority; (d) make available upon request of a former employee a report of the employee's exposure to radiation; (e) at request of an employee advise the employee of his or her annual radiation exposure; and (f) inform each employee in writing when the employee has received radiation exposure in excess of the prescribed limits.

The NRC staff review verified that Minnesota has adopted rules compatible with 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150. The records and reports referenced in Criterion 11 are regulatory requirements in these parts. Minnesota has adopted the record and reporting requirements.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety.

12. Additional Requirements and Exemptions. Consistent with the overall criteria here enumerated and to accommodate special cases and circumstances, the State regulatory authority shall be authorized in individual cases to impose additional requirements to protect health and safety, or to grant necessary exemptions which will not ieopardize health and safety.

The NRC staff review confirmed that Minnesota State law provides the radiation control agency authority to impose, by order or license condition, additional health and safety requirements beyond the requirements specified in law and the rules. The agency also has the legal authority to grant reasonable and necessary exceptions to the regulatory requirements, either by order or

license condition. Minnesota has adopted a rule which is compatible with 10 CFR 30.34, Terms and conditions of licenses.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1 and 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), Mn. Stats. 144.12 and 144.99 and Chapter 4731 Radiation Safety, Section 4731.3075.

PRIOR EVALUATION OF USES OF RADIOACTIVE MATERIALS

13. Prior Evaluation of Hazards and Uses, Exceptions. In the present state of knowledge, it is necessary in regulating the possession and use of byproduct, source and special nuclear materials that the State regulatory authority require the submission of information on, and evaluation of, the potential hazards, and the capability of the user or possessor prior to his receipt of materials. This criterion is subject to certain exceptions and to continuing reappraisal as knowledge and experience in the atomic energy field increase. Frequently there are, and increasingly in the future there may be, categories of materials and uses as to which there is sufficient knowledge to permit possession and use without prior evaluation of the hazards and the capability of the processor and user. These categories fall into two groups-- those materials and uses which may be completely exempt from regulatory controls, and those materials and uses in which sanctions for misuse are maintained without pre-evaluation of the individual possession or use. In authorizing research and development or other activities involving multiple uses of radioactive materials, where an institution has people with extensive training and experience, the State regulatory authority may wish to provide a means for authorizing broad use of materials without evaluating specific use.

Minnesota has adopted regulations containing regulatory requirements for applying for and issuing licenses, which are compatible with NRC's regulations.

The NRC staff review confirmed that the Minnesota rules provide that a license authorizing the distribution of agreement materials that will subsequently be exempt from regulatory control may only be issued by the NRC.

Since Criterion 13 was adopted, the Commission has determined that the regulatory authority to conduct safety evaluations of sealed sources and devices may be retained by the NRC, unless the State requests assumption of the authority and has in place an adequate and compatible program to implement the authority. Minnesota has decided not to seek authority for evaluation of sealed sources and devices.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the

State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), Chapter 4731 Radiation Safety.

14. Evaluation Criteria. In evaluating a proposal to use radioactive materials, the regulatory authority shall determine the adequacy of the applicant's facilities and safety equipment, his training and experience in the use of the materials for the purpose requested, and his proposed administrative controls. States should develop guidance documents for use by license applicants. This guidance should be consistent with NRC licensing regulatory guides for various categories of licensed activities.

The NRC staff review determined that the Minnesota Program has established series of checklists, regulatory guides and licensing procedure guides and a set of applicable forms. Minnesota has developed a series of State developed regulatory guides for use by license applicants. The NRC staff determined that the licensing procedure guides cover the handling of license applications from the point of submittal through issuance of the completed license. The Minnesota licensing procedures are similar to NRC's procedures.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.3, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240).

15. Human Use. The use of radioactive materials and radiation on or in humans shall not be permitted except by properly qualified persons (normally licensed physicians) possessing prescribed minimum experience in the use of radioisotopes or radiation.

In April 2004, the NRC amended 10 CFR Part 35 to change its requirements for recognizing specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience (T&E) of individuals to serve as Radiation Safety Officers, authorized medical physicists, authorized nuclear pharmacists, or authorized (physician) users. The final rule also revises the requirements for demonstrating the adequacy of T&E for pathways other than the board certification pathway. Agreement States are required to adopt a compatible rule. In a letter dated May 25, 2005, the Manager of the Asbestos, Indoor Air, Lead and Radiation Section, responding to NRC staff comments, committed to incorporating the new Part 35 requirements in their program as a license condition and in their appropriate guidance documents.

Based on this commitment, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), Chapter 4731 Radiation Safety, §§ 4731.4400-4731.4527.

INSPECTION

16. Purpose, Frequency. The possession and use of radioactive materials shall be subject to inspection by the regulatory authority and shall be subject to the performance of tests, as required by the regulatory authority. Inspection and testing is conducted to determine and to assist in obtaining compliance with regulatory requirements. Frequency of inspection shall be related directly to the amount and kind of material and type of operation licensed, and it shall be adequate to insure compliance.

The NRC staff confirmed that the Minnesota Program has statutory authority to conduct inspections of licensees. Minnesota has adopted regulations compatible with equivalent parts of 10 CFR containing provisions relating to inspections and tests.

Minnesota has adopted a schedule for inspection of licensees at least as frequent as the schedule used by NRC. The Program staff has developed internal procedures and accompanying forms for the inspection areas which cover scheduling, preparation, performance basis, tracking and documentation of inspection results. The Program staff has also established a computerized tracking system. The inspection procedures are similar to NRC procedures.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Sections 4.1, Mn. Stat. 144.99, and Section 4.4, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240).

17. Inspections Compulsory. Licensees shall be under obligation by law to provide access to inspectors.

The NRC staff review confirmed that Minnesota law provides authority for radiation control Program inspectors to enter public or private property at all reasonable times for the purpose of investigating conditions related to radiation use.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, Mn. Stat. 144.99, and Section 4.4, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240).

18. Notification of Results of Inspection. Licensees are entitled to be advised of the results of inspections and to notice as to whether or not they are in compliance.

The NRC staff review determined that Minnesota has adopted procedures to convey a copy of the formal inspection report to the licensees, both when violations are found, and when no violations are found. The procedures identify the staff responsible and specify the time limit for preparing the inspection report, the process for management review and approval, and provide instructions for distribution of the report to the licensee and to the State's official files.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.4, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240).

ENFORCEMENT

19. Enforcement. Possession and use of radioactive materials should be amenable to enforcement through legal sanctions, and the regulatory authority shall be equipped or assisted by law with the necessary powers for prompt enforcement. This may include, as appropriate, administrative remedies looking toward issuance of orders requiring affirmative action or suspension or revocation of the right to possess and use materials, and the impounding of materials; the obtaining of injunctive relief; and the imposing of civil or criminal penalties.

The NRC staff review confirmed that the Minnesota Program is authorized by law to enforce the State rules using a variety of sanctions, including the imposition of administrative fines, and the issuance of orders to suspend, modify or revoke licenses, or to impound materials. The Program may assess civil penalties in accordance with State Law and Department regulations.

The Program has adopted policies and procedures to implement the enforcement authority. The Minnesota enforcement procedures are similar to the NRC procedures with regard to the use of severity levels for violations.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, Mn. Stats. 144.12, 144.99, and Section 4.5, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240).

PERSONNEL

20. Qualifications of Regulatory and Inspection Personnel. The regulatory agency shall be staffed with sufficient trained personnel. Prior evaluation of applications for licenses or authorizations and inspections of licensees must be conducted by persons possessing the training and experience relevant to the type and level of radioactivity in the proposed use to be evaluated and inspected. This requires competency to evaluate various potential radiological hazards associated with the many uses of radioactive material and includes concentrations of radioactive materials in air and water, conditions of shielding, the making of radiation measurements, knowledge of radiation instruments—their selection, use and calibration—laboratory design, contamination control, other general principles and

practices of radiation protection, and use of management controls in assuring adherence to safety procedures. In order to evaluate some complex cases, the State regulatory staff may need to be supplemented by consultants of other State agencies with expertise in geology, hydrology, water quality, radiobiology and engineering disciplines.

To perform the functions involved in evaluation and inspection, it is desirable that there be personnel educated and trained in the physical and/or life science, including biology, chemistry, physics and engineering, and that the personnel have had training and experience in radiation protection. For example, the person who will be responsible for the actual performance of evaluation and inspection of all of the various uses of byproduct, source and special nuclear material which might come to the regulatory body should have substantial training and extensive experience in the field of radiation protection. It is desirable that such a person have a bachelor's degree or equivalent in the physical or life sciences, and specific training - radiation protection.

It is recognized that there will also be persons in the program performing a more limited function in evaluation and inspection. These persons will perform the day-to-day work of the regulatory program and deal with both routine situations as well as some which are out of the ordinary. These people should have a bachelor's degree or equivalent in the physical or life sciences, training in health physics, and approximately two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition. there will probably be trainees associated with the regulatory program who will have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in the field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These trainees, of course, could be used initially to evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint, for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, the trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree or equivalent in the physical or life sciences and specific training in radiation protection. In determining the requirement for academic training of individuals in all of the foregoing categories, proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

It is recognized that radioactive materials and their uses are so varied that the evaluation and inspection functions will require skills and experience in the different disciplines which will not always reside in one person. The regulatory

authority should have the composite of such skills either in its employ or at its command, not only for routine functions, but also for emergency cases.

Based on the review of the organizational charts and position descriptions for the Minnesota Program, training and qualification plan, and the curricula vitae for the current staff members, the NRC staff concludes that the RCU has a staffing plan that provides a sufficient number of adequately trained and qualified technical staff.

1. Draft Staff Assessment of the Agreement Materials Staffing

There are approximately 167 NRC specific licenses in Minnesota. The RCU also conducts a registration and inspection program for NARM users which accounts for approximately 45 registrants.

The staff of the RCU will be responsible for implementing the agreement materials program. The Minnesota staffing plan allocates a total of approximately 5.0 full-time equivalent (FTE) staff for the agreement materials program, including the Program Supervisor. Since submission of the Agreement request, one staff member has left the Program. This position was filled with a new hire in December 2004. The RCU supervisor plans to devote 50% of his time to the agreement materials program, including management review of licensing and inspection actions, personnel responsibilities, rules development, accompaniment of inspectors for annual management review, general supervision, and other management duties. Four staff members will devote 100% of their time to the Agreement State Program activities and one other staff member will provide 30%. Minnesota's staff assessment used 80% of the full-time employees' time in their staffing analysis. They assume that the other 20% of the employees' time will be devoted to radiological response, instructional opportunities and training. One full-time administrative assistant provides support to the Program.

Based on the RCU staffing allocation of 5.0 technical and administrative FTE for the Program, and subtracting the Program Supervisor and administrative assistants, the technical/professional staffing level devoted to the Agreement State Program is 3.5 FTE. The Team's evaluation of the State's staffing analysis concludes that adequate staffing exists without the new hire's FTE. The RCU supervisor is using this additional FTE to provide flexibility and backup to the radioactive materials program.

Minnesota estimates they will have responsibility for 210 licenses (167 from NRC and 45 existing NARM registrants). The RCU Staff Resource Analysis projects that approximately 172 licensing staff days will be needed and 259 licensing staff days are available; 368 inspection staff days are needed and 531 are available each year. This projection is based on data from the NRC Region III Office. This level of inspection effort will keep the inspection program current.

Based on the workload analysis, NRC staff concludes the initial 3.5 FTE qualified technical\professional staff provides an adequate level of staffing to handle anticipated licensing, inspection, reciprocity, allegations and incident response workload satisfactorily.

The staff concludes that the proposed Minnesota agreement materials program has an adequate number of staff to meet the anticipated Program needs.

2. Draft Staff Assessment of Staff Qualifications

The NRC staff review considered the qualifications of the individuals currently on the RCU's professional/technical staff that would be involved in the agreement materials program, and the procedures for training and qualifying new staff members. Under the proposed Agreement, the RCU Supervisor would direct the agreement materials program and would be primarily responsible for the Program's administration and will provide the immediate day-to-day supervision of the agreement materials program. He holds a Bachelor's degree in Physics and Philosophy. He has over 20 years of experience in health physics and supervision. He has 10 years of experience in an agreement material program from another State and 10 years of radiological experience in the U.S. Navy.

Based on the NRC staff review, three of the five non-supervisory staff members have at least a Bachelor's degree in physical life sciences or engineering. One staff member has a Master's degree in public health and a Bachelor's degree in engineering; one staff member has a Bachelor's degree in applied studies concentration in radiological science and an Associate degree in radiologic technology; one staff member has a Master's degree in materials science engineering, a Bachelor's degree in chemistry, and a Bachelor's degree in chemical engineering; and the two other staffers are former radiologic technologists with significant experience and training in radiation protection.

The RCU technical staff members have extensive radiation science experience. This includes work in health physics and nuclear power in private industry, the military and in State regulatory agencies. Technical staff members have completed the NRC-recommended core courses or have received waivers from the RCU manager, based on their training and prior experience. The new hire has taken the inspection and licensing courses and is scheduled to attend the remaining core training courses in the next year.

Two technical staff have had on-the-job training working with NRC license reviewers in the NRC Region III Office and all of the fully qualified technical staff members have accompanied NRC staff on inspections of NRC licensees in Minnesota. Several of the technical staff have also spent time in neighboring Agreement States receiving licensing and inspection training.

The NRC staff believes that the RCU technical staff identified by the State to participate in the agreement materials program are trained and qualified in accordance with the RCU plans, have sufficient knowledge and experience in radiation protection, the use of radioactive materials, the standards for the evaluation of applications for licensing, and the techniques of inspecting licensed users of agreement materials.

The staff concludes that the proposed Minnesota Program has a sufficient number of adequately trained staff to meet the anticipated program needs. The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Sections 4.6, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240).

21. Conditions Applicable to Special Nuclear Material, Source Material and Tritium. Nothing in the State's regulatory program shall interfere with the duties imposed on the holder of the materials by the NRC, for example, the duty to report to the NRC, on NRC prescribed forms, (1) transfers of special nuclear material, source material and tritium, and (2) periodic inventory data.

The NRC staff review did not note any aspects of the Minnesota Program that could potentially interfere with duties imposed on a holder of materials by the NRC. In addition, Minnesota's regulations specifically exempt areas of exclusive NRC or other Federal jurisdiction from State regulation. The staff is therefore satisfied that the Minnesota Program will not interfere with duties imposed on the holder of materials by the NRC.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1, Statutory Authority and Section 4.1.2, Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats. 115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

22. Special Nuclear Material Defined. Special nuclear material, in quantities not sufficient to form a critical mass, for present purposes means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear material in combination should not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

175 (grams contained U-235)/350 + 50 (grams U-233)/200 + 50 (grams PU)/200 = 1

The NRC staff determined that Minnesota's definition of special nuclear material in critical mass quantities in 4731.0315, *Critical Mass*, is compatible with that of the Commission's.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1, Statutory Authority and Section 4.1.2, Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384,

ML051650073, ML0522004240), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats. 115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

ADMINISTRATION

- 23. Fair and Impartial Administration. State practices for assuring the fair and impartial administration of regulatory law, including provision for public participation where appropriate, should be incorporated in procedures for:
 - a. Formulation of rules of general applicability;
 - b. Approving or denying applications for licenses or authorization to process and use radioactive materials; and
 - c. Taking disciplinary actions against licensees.

The NRC staff review confirmed that the MDH is bound by general statutory provisions with respect to providing the opportunity for public participation in rulemaking, licensing actions, and disciplinary actions. These general statutory provisions also apply to the protection of personnel radiation exposure records from public disclosure, maintaining the confidentiality of allegers, and administrative and judicial requirements for requesting and holding hearings on enforcement matters.

The staff concludes that this criterion is satisfied

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, Mn. Stat. 144.99, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following: Mn. Stat. 14.05 through 14.28.)

24. State Agency Designation. The State should indicate which agency or agencies will have authority for carrying on the program and should provide the NRC with a summary of that legal authority. There should be assurances against duplicate regulation and licensing by State and local authorities, and it may be desirable that there be a single or central regulatory authority.

The NRC staff determined that the MDH is designated by Mn. Stat. 144.1202 to be the lead agency for the carrying out the terms of the proposed Agreement, which will assure against duplicate regulations or licensing by State and local authorities. In addition, to the extent that this criterion deals with duplicate regulation between a State and the NRC (see STP Procedure SA-700 Handbook, Evaluation Criteria 4.1.1.2., paragraph b, and 4.2.2.2), the staff determined that the Minnesota Program, which specifically excludes from State regulation any areas in which the jurisdiction of the NRC or another Federal agency is exclusive, gives sufficient assurance against duplicate regulation between Minnesota and the NRC in the regulation of agreement material.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1, Statutory Authority and Section 4.1.2, Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats. 115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

25. Existing NRC Licenses and Pending Applications. In effecting the discontinuance of jurisdiction, appropriate arrangements will be made by NRC and the State to ensure that there will be no interference with or interruption of licensed activities or the processing of license applications by reason of the transfer. For example, one approach might be that the State, in assuming jurisdiction, could recognize and continue in effect, for an appropriate period of time under State Law, existing NRC licenses, including licenses for which timely applications for renewal have been filed, except where good cause warrants the earlier reexamination or termination of the license.

The NRC staff review confirmed that Mn. Stat. 144.1202 contains a provision that deems the holder of an NRC license on the effective date of the proposed Agreement to possess a like license under the Minnesota Radiation Safety Code. The license will expire on the expiration date on the NRC license.

The staff concludes that this criterion is satisfied

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1. Mn. Stat. 144.1202, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240).

26. Relations with Federal Government and Other States. There should be an interchange of Federal and State information and assistance in connection with the issuance of regulations and licenses or authorizations, inspection of licensees, reporting of incidents and violations, and training and education problems.

The NRC staff review verified that the proposed Agreement commits Minnesota to cooperate with the NRC and the other Agreement States in the formulation of standards and regulatory programs for the protection against hazards of radiation and to assure that the Minnesota Program will continue to be compatible with the NRC's program for the regulation of agreement materials.

In a revised Policy Statement on Adequacy and Compatibility of Agreement State Programs (published September 3, 1997 at 62 FR 46517), the Commission determined that providing

reports to NRC of Agreement State licensee incidents, accidents and other significant events is a matter of compatibility. Minnesota has adopted procedures to provide such reports to NRC.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and the Section 4.1. reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400), and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf. The Minnesota response to NRC's comments on the final application dated December 14, 2004 (ADAMS: ML050130375).

- 27. Coverage, Amendments, Reciprocity. An amendment providing for discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State may relate to any one or more of the following categories of materials within the State, as contemplated by Public Law 86-373 and Public Law 95-604:
 - a. Byproduct material as defined in Section 11e(1) of the Act,
 - b. Byproduct material as defined in Section 11e(2) of the Act,
 - c. Source material,
 - d. Special nuclear material in quantities not sufficient to form a critical mass,
 - e. Low-level wastes in permanent disposal facilities, as defined by statute or Commission rules or regulations containing one or more of the materials stated in a, c, and d above but not including byproduct material as defined in Section 11e(2) of the Act;

but must relate to the whole of such category or categories and not to a part of any category. If less than the five categories are included in any discontinuance of jurisdiction, discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State of the others may be accomplished subsequently by an amendment or by a later Agreement.

Arrangements should be made for the reciprocal recognition of State licenses and NRC licenses in connection with out-of-jurisdiction operations by a State or NRC licensee.

The NRC staff review verified that the proposed Agreement provides for the Commission to discontinue, and the State of Minnesota to assume, regulatory authority over the types of material defined in categories a, c, and d above.

Since this criterion was adopted, the Commission has determined that the Agreement States may assume the authority to evaluate the safety of sealed sources and devices to be distributed

in interstate commerce as a separate portion of the Agreement, or to allow NRC to retain that authority. Minnesota has chosen not to assume that authority.

References: Proposed Agreement between the State of Minnesota and the Nuclear Regulatory Commission, Articles I, II, and III in the request for an Agreement by Governor Pawlenty.

The proposed Agreement stipulates the desirability or reciprocal recognition of NRC and other Agreement State licenses, and commits the Commission and the State to cooperate to accord such reciprocity. Minnesota's regulation provides for the reciprocal recognition of licenses from other jurisdictions.

References: Proposed Agreement between the State of Minnesota and the Nuclear Regulatory Commission, Article VII; Mn. Reg. 4731.0355.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and the Section 4.1. reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400), and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

- 28. NRC and Department of Energy Contractors. The State should provide exemptions for NRC and DOE contractors which are substantially equivalent to the following exemptions:
 - a. Prime contractors performing work for the DOE at U.S. Government-owned or controlled site;
 - b. Prime contractors performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;
 - c. Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and
 - d. Any other prime contractor or subcontractor of DOE or NRC when the State and the NRC jointly determine (i) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; and (ii) that the exemption of such contractor or subcontractor is authorized by law.

The NRC staff review verified that Minnesota has adopted 10 CFR Parts 30, 40 and 70 compatible rules including §§ 30.12, 40.11 and 70.11 wherein the specified exemptions are

contained. Based on this, the NRC staff concludes that the Minnesota regulations do provide for exemptions from the State's requirements for licensing of sources of radiation for NRC and DOE contractors or subcontractors in accordance with the criterion.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML0522004240), and Chapter 4731 Radiation Safety.

STAFF CONCLUSION

The NRC staff has reviewed the proposed Agreement, the certification by Minnesota in the application for an Agreement in letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, and the supporting information provided by the staff of the RCU of the MDH.

Subsection 274d of the Act provides that the Commission shall enter into an Agreement under Subsection 274b with any State if:

- (a) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect public health and safety with respect to the agreement materials within the State, and that the State desires to assume regulatory responsibility for the agreement materials; and
- (b) The Commission finds that the State program is in accordance with the requirements of Subsection 274o, and in all other respects compatible with the NRC's program for the regulation of materials, and that the State program is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

The staff concludes that:

On the basis of the Draft Staff Assessment, the State of Minnesota meets the requirements of the Act. The Minnesota Program, as defined by its statutes, regulations, personnel, licensing, inspection, and administrative procedures, is compatible with the program of the NRC and adequate to protect public health and safety with respect to the materials covered by the proposed Agreement. Although the State has statutes, not a part of the Minnesota Program, which potentially intrude on matters reserved to the NRC, these statutes do not deal with the regulation of agreement materials, and the staff is satisfied that these statutes will not affect or interfere with the regulation of materials under the proposed Agreement.

As a policy matter, if the NRC enters into an Agreement with the State of Minnesota, it will not in any way be precluded in the future from taking up with the State its regulation in matters potentially reserved to the NRC, because the NRC is ceding no authority to Minnesota in the areas covered by the Minnesota statutes in question. There is no indication that Minnesota statutes have actually interfered with the regulation of reactors or other matters in which the NRC has exclusive jurisdiction, and the staff is satisfied that there is no actual or potential

health, safety, or security significance with respect to the Minnesota statutes in question, nor have affected licensees raised any preemption issues with respect to the Minnesota statutes.

In addition, the policy consequences of refusing to enter into an Agreement with Minnesota on the basis of these statutes are considerable. First of all, to do so would contradict the Commission's stated policy on compatibility, as found in the Commission's 1997 Policy Statement, which in the definition of compatibility restricts the scope of compatibility to the regulation of agreement materials. Second, to consider statutes which are not part of a State's submitted program for the regulation of material under the Agreement would go beyond the scope of the Agreement itself and force the staff, before entering into an Agreement, to perform a wide-ranging search of State statutes and regulations that have little or nothing to do with regulation of materials under the proposed Agreement. In addition, this experience will likely prove extremely frustrating to Minnesota and could potentially discourage other States to enter into Section 274b agreements with the NRC, being that State executive governments will often have little direct control over statutes enacted by the State Legislatures that are separate from the States' proposed program for the regulation of agreement materials.

NRC will continue the formal processing of the proposed Agreement which includes publication of a Federal Register Notice of the proposed Agreement once a week for four consecutive weeks for public review and comment.